HFA-305

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

AUG 15 2000

Mr. Thomas G. Crouthamel, Sr.
Box 6459
Bradenton, Florida 34281

Re: 00P-0804/CP1

Dear Mr. Crouthamel:

This letter is in response to your citizen petition dated February 22, 2000. In the petition, you request that the Food and Drug Administration (FDA) issue a regulation requiring additional labeling for cucumber pickle products containing the colors FD&C Yellow #5 or FD&C Blue #1. Specifically, you maintain that manufacturers or re-packers of such products should be required to place a legend on the principal display panels stating that these products are "artificially colored." You propose that the letters of this legend be the same size and color as the net weight statement. In support of your request, you contend that, although the two color additives to which you refer may be listed in a product's ingredient statement, consumers may nonetheless be deceived into believing that the green color of such pickle products is natural in an "old-fashioned" sense.

FDA recognizes that some consumers are interested in knowing whether the foods they consider purchasing contain added color. As you acknowledge in your petition, 21 CFR §101.22(k) provides that the label of a food to which any coloring has been added must declare the coloring in the statement of ingredients. You argue, in essence, that this labeling requirement does not suffice to inform consumers that pickle products containing colors FD&C Yellow #5 and FD&C Blue #1 are not naturally green-colored. You have not, however, submitted any data or other information demonstrating that the ingredient statement provides insufficient information to consumers about the artificial colors that are included in those products, nor is FDA aware of any such data or information. In the absence of substantiation of this sort, you have not shown that there are reasonable grounds for your proposed regulation or that the proposed regulation is in

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the public interest and will promote the objectives of the act or the agency. See 21 CFR 10.40(a)(2). Therefore, in accordance with 21 CFR §10.30(e)(2), the purpose of this letter is to advise you that FDA is denying your petition without prejudice.

Thank you again for your interest, and we hope this information has been helpful to you.

Sincerely yours,

Dennis E. Baker
Associate Commissioner
for Regulatory Affairs